

**United States District Court  
Northern District of California**

**Case No.: 3:18-cv-01586-JSC**

**IN RE PACIFIC FERTILITY CENTER LITIGATION**

**Expert Report of Dr. Stephen G. Somkuti**

**October 14, 2019**

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## **I. ASSIGNMENT**

1. I have been retained as an expert witness by interim class counsel and counsel for several individuals who stored their eggs and embryos in a tank located at Pacific Fertility that failed in or about March 4, 2018, and their reproductive partners.

2. I was engaged to provide insight as to the nature of the in vitro fertilization (IVF) process, in addition to the IVF experience. I am not an expert in egg and embryo storage, although I have a generalized knowledge of lab standards and best practices obtained through my experience as a reproductive endocrinologist.

3. I relied on the materials listed in **Exhibit A** to generate my opinions.

4. My hourly rate is \$7,500 per day for deposition testimony and \$500 per hour for non-testimony work I perform for this matter. I am being compensated for my time as an expert witness and this compensation is in no way contingent on the outcome of the case.

## **II. QUALIFICATIONS**

5. I hold a current, valid, and unrestricted medical license in Pennsylvania. I am certified by the American Board of Obstetrics and Gynecology as an Obstetrician Gynecologist with subspecialty certification in the field of Reproductive Endocrinology and Infertility and have been certified and recertified since 1995. I am actively engaged full-time in the clinical practice of reproductive endocrinology at Abington Reproductive Medicine. I am also Director of the Division of Reproductive Endocrinology in the department of Obstetrics and Gynecology at Abington Memorial Hospital. I am Professor of Obstetrics and Gynecology at the Temple University School of Medicine. My review of the matters of this case is limited to the areas of my sub-specialty regarding the issues related to this lawsuit. A copy of my current curriculum vitae is attached hereto as **Exhibit B**.

6. I have reviewed the current concepts and practices related to my sub-sociality, as well as the concepts and practices related to that standard at the time of the occurrence that led to the lawsuit. All of my opinions are stated with a reasonable degree of professional certainty based upon my knowledge and practice of reproductive endocrinology. I am willing to have my testimony submitted for peer review.

### **III. OVERVIEW OF IVF**

#### **A. Relevant Background**

7. *In vitro* fertilization, also known as IVF, is the process of retrieving an egg and combining it with sperm outside of the body. The Latin term for “in the body” is “*in vivo*”, while outside of the body is “*in vitro*”. Essentially, sperm and eggs are incubated together in a petri dish, embryos are created, then the resulting embryo(s) is transferred into the woman’s uterus. The process of IVF is time consuming and invasive.

8. The first IVF success was recorded in 1978 with the birth of Louise Brown in the United Kingdom. IVF has now become a routine procedure, with over 5 million babies having been born worldwide. Close to 250,000 cycles of IVF are performed each year resulting in over 75,000 live infants being born.

9. IVF clients may freeze and store sperm, eggs (oocytes), and embryos with the advent of cryopreservation technologies. Liquid nitrogen maintains the integrity of these specimens at very low temperatures in special storage tanks. Specimens may be stored for many years without damage to them. Freezing of these biological materials offers a significant advantage and “peace of mind” to people who want to undergo IVF. They may now delay childbearing, while avoiding the negative impact the aging process has on fertility and egg

quality that results in lower pregnancy rates. Likewise, following a successful IVF pregnancy, they may return years in the future to have another child.

**B. The IVF Experience**

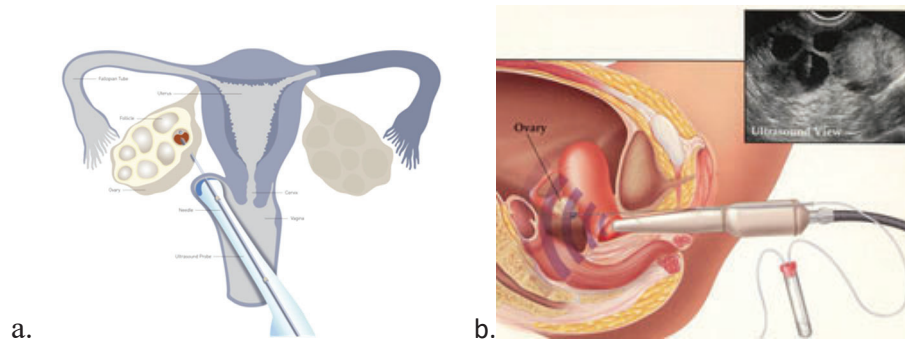
10. IVF is taxing on individuals undergoing IVF and their partners, both physically and mentally, and involves a significant commitment of time as well as money. The first step is to do a basic assessment of a prospective IVF client's need for IVF by a reproductive endocrinologist. This initial assessment includes diagnostic tests such as transvaginal ultrasounds to look for fibroids, polyps, scar tissue or other anatomic anomalies within the uterus, blood draws to assess ovarian reserve, a saline sonogram or x-ray called a hysterosalpingogram (HSG) to assess the patency of the tubes and image the uterine cavity, endometrial biopsy, a telescope to look inside the uterus (hysteroscopy) to diagnose and treat any abnormalities in the uterine cavity, and ultrasounds and blood tests to determine if a woman ovulates or not, or has cysts or other ovarian pathology. All of this testing requires time; some of the tests are rather painful, uncomfortable and invasive. Costs can be expensive and prohibitive depending on what insurance may or may not cover.

11. Once the initial testing and screening is completed, the process of IVF may begin. Fertility medications are prescribed to stimulate egg production. For IVF, these are injectable forms of Follicle-stimulating hormone (FSH). Daily injections will stimulate multiple eggs to develop within cysts known as follicles. Additional hormone shots are also required to block the lutenizing hormone surge that would initiate ovulation. These are known as GnRH agonist or antagonists. Without these shots, a woman would be at risk of ovulating prior to the retrieval resulting in no eggs being collected. The woman will have multiple monitoring visits with her REI consisting of transvaginal ultrasounds and hormone level evaluations leading up to the egg

retrieval. Visits may even become daily to precisely time the egg retrieval. Once maturity criteria are met, a “trigger shot” which contains  $\beta$ -hCG, (meant to mimic the LH surge in a natural menstrual cycle), will be administered. The woman would then be scheduled for the retrieval, which occurs approximately 36 hours later. These are very time-sensitive procedures; therefore IVF clinics are typically open 7 days a week, including weekends and holidays for retrievals and embryo transfers.

12. The side effects of IVF medications are numerous. They include hot flashes, fatigue, headaches, pain, peripheral edema, nausea, vomiting, bloating, weight gain, injection site reactions (soreness, bruising, irritation, redness, pain), breast swelling/ tenderness/ pain, numbness and tingling feelings, runny or stuffy nose, sore throat, acne, skin rashes, mild stomach and abdominal pain, pelvic pain and tenderness, allergic reactions, and dizziness.

13. Eggs are retrieved through a surgical procedure that uses ultrasound imaging to guide a hollow needle through the back vaginal wall into the ovary to remove the eggs. The woman is given sedation anesthesia for the procedure. The ultrasound probe that has been used for the monitoring of the follicle sizes now has a long large gauge needle attached to it which is introduced by the REI through the back of the vagina (see graphic a) into each one of the fluid filled cysts (follicle) containing an oocyte (see graphics a and b). Using gentle suction, the follicle fluid is sucked into a test tube (see graphic b) that an assistant will then give to the embryology staff. This is the point that a “handoff” occurs, meaning the REI physician has obtained the fluid containing the oocytes and now has given this to the embryologist.



14. The room in which the REI extracts eggs from the woman is typically directly connected to the embryology lab by a window so that the test tubes containing eggs may be handed off to the embryologist and examined under a microscope in real time. The woman recovers and then is discharged.

15. The embryologist assumes the responsibility of biological materials once the test tube specimen containing the aspirated fluid has been handed over from the IVF retrieval. It is now the embryologist that shepherds the eggs through the next steps. These plans may involve oocyte freezing, oocyte fertilization with sperm or using intracytoplasmic injection (ICSI) to inject sperm into the egg, assisted hatching (thinning of the embryo shell to enhance implantation), extended embryo culture up to day 6 of development, freezing of embryos, and embryo biopsy for determining the chromosomal makeup of the embryo (PGS) or for evaluation of carrier status of single gene diseases (PGD). If the eggs are to be fertilized rather than stored, the male partner will be required to give a sperm sample (unless donor sperm is used). This is sent to the embryologist for washing. Sperm washing is the process of removing all seminal fluid, which leaves only the most mobile and healthy sperm.

16. Once the fluid is aspirated from the follicles, retrieved eggs must be identified. Sperm are also washed and prepared. The surrounding cells are removed from the eggs if ICSI is

to be performed. If oocytes are immature, then there are techniques that may mature them in culture. Only a mature oocyte is able to be fertilized. Approximately five to six hours after retrieval, several thousand moving sperm are either added to a droplet of culture media containing each egg (insemination), or – in cases where ICSI is being used – a single sperm is actually injected directly into each egg by the embryologist using a tiny needle directed by robotically controlled instruments. The eggs are then returned to their incubator for 18 hours of development, during which time fertilization hopefully occurs.

17. If the plan is oocyte freezing, then the embryologist will prepare the eggs with the appropriate cryoprotectant solutions, load oocytes into straws and then put the eggs through a programmed freezing protocol before transferring them to storage tanks. If the plan is to create embryos for transfer back into the woman, then sperm and oocytes are prepared for fertilization with appropriate in vitro culture solutions providing the micronutrients needed for optimizing embryo development. Embryos are kept in temperature- and atmosphere-controlled incubators for anywhere from three to six days. Over the course of the following week, while the embryologists monitor and maintain the culture media, gas atmosphere, humidity and temperature levels in the incubators that house the embryos, the embryos begin to divide and develop.

18. A fresh embryo transfer typically occurs between days 3 to 6 of development, with the majority occurring on day 5 or 6. If the plan is to freeze all embryos, this is the first day that we start this process. Embryos are assessed for vitrification. For those IVF clients who desire genetic testing of their embryos, this is the typical day that embryo biopsies are performed.



19. The IVF process is expensive. The cost of medications may easily exceed \$3,000 to \$5,000 for a single cycle of IVF. The fees associated with IVF, accounting for monitoring, laboratory fees, anesthesia, and retrieval related fees may exceed \$10,000 for a single cycle. Genetic testing of embryos adds an additional cost of \$3,000 to \$5,000. All total, upwards of \$15,000 to 20,000 may be spent on a single cycle of IVF.

20. The IVF process is also emotionally charged and physically demanding. This starts with the initial IVF consult where the process is explained to the IVF client(s). Those undergoing IVF must answer difficult questions and address complex “what if” situations that may be confronted, such as, “what do you want to do with the frozen embryos if someone dies,” becomes divorced, etc. The emotionally charged nature of IVF is amplified by the fact that the hormones and medications used in IVF result in significant mood swings. There are psychologists and therapists who specialize in reproductive issues and support groups for couples.

21. IVF failure, whether manifested as failure to produce viable embryos or failure to produce a child upon transfer of an embryo, amplifies the emotional costs associated with IVF, and may subject the IVF client to a new round of medical and emotional risks as additional IVF attempts are made.

22. Because IVF poses risks to the emotional health and relationships of those who are undergoing the process (including reproductive partners), embryologists should undergo strict training and their laboratories should adhere to standards and practices that are reflective of the importance of the eggs and embryos to those who have undergone IVF. The quality of the IVF laboratory is critical. The training and experience of the embryology staff, the protocols

used for embryo culture, air quality, and state of the art equipment (that works) are recognized metrics impacting IVF outcomes.

23. Those responsible for storage of vitrified eggs and embryos must also adhere to strict protocols and best practices, again because of the lengths to which people have gone to create the eggs and embryos. Maintaining controlled, cold temperatures is critical to egg and embryo storage because, in the event of an uncontrolled thaw, there are unknown factors as to risks of birth defects and toxic effects due to unintended extended exposure of oocytes and embryos to the cryoprotectants they are surrounded by when vitrified.

### **C. IVF Professionals, Their Roles and Responsibilities**

#### **1. Reproductive Endocrinology and Infertility Doctors**

24. Reproductive Endocrinology and Infertility (REI) is a subspecialty within Obstetrics and Gynecology. It requires a four-year residency in OB/GYN followed by a three-year sub-specialty fellowship and an additional board examination. Once completed, written and oral specialty examinations and follow up recertification examinations result in board (re)-certification in the subspecialty of REI.

25. The REI is responsible for the initial evaluation of the IVF client and forming a therapeutic strategy. A set of recommendations often involve invasive imaging studies of the female reproductive system. A battery of blood tests and a semen analysis for the male partner are ordered to help formulate the most appropriate plan to optimize chances for success. The REI also extracts eggs as described above, and then hands them off to the embryologist.

#### **2. Embryologists**

26. Embryologists are responsible for identifying the eggs collected from a retrieval, assisting with in vitro fertilization, maintaining clinical records and running tests on embryos.

They often work in hospitals and fertility clinics, but may also perform laboratory work or seek posts in academia.

27. Embryologists are required to have a bachelor's degree in biology or biomedicine. Advanced embryologists may have a master's degree in reproductive science or clinical science, and some embryologists complete a Ph.D. or M.D/D.O. as well. Laboratory directors with a doctorate may obtain an H.C.L.D., which is a High Complexity Laboratory Director certification.

28. The responsibilities of an embryologist include identification of oocytes and preparing them for insemination, preparing sperm for artificial insemination or for fertilization of the oocytes, conducting ICSI, cryopreserving embryos, and transferring embryos. Embryologists are also responsible for laboratory maintenance such as preparing the filters, medias and supplies used during the collection of oocytes, for rinsing, searching, and washing specimens, and for accurately grading embryos according to protocols. They also freeze embryos for storage in liquid nitrogen and oversee the maintaining of storage tank temperatures and the inventories of these embryos. Laboratory quality control, air quality, sterile technique, safe handling and labeling of specimens are all integral parts of embryology. Embryologists also calculate pregnancy rate statistics.

#### **IV. CONCLUSIONS**

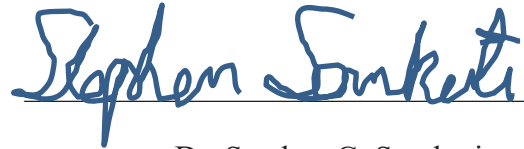
29. I conclude the following to a reasonable degree of professional certainty.

30. IVF involves significant investments of time and money, and is demanding—both physically and emotionally.

31. Because: (1) IVF is a difficult process, and (2) eggs and embryos are important to those who have undergone IVF, it is critical for embryologists and embryology laboratories to

adhere to best practices and maintain vitrified eggs and embryos in a carefully controlled environment, with redundant systems, and appropriate safeguards in place.

I declare under penalty of perjury under the laws of the United States that the above is true and correct. Executed on October \_\_, 2019 in Abbington, Pennsylvania.

A handwritten signature in blue ink, reading "Stephen Somkuti", is written over a horizontal line.

Dr. Stephen G. Somkuti

**EXHIBIT A****References**

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**EXHIBIT B**

## CURRICULUM VITAE

NAME Stephen G. Somkuti, M.D., Ph.D., F.A.C.O.G.

ADDRESS Abington Reproductive Medicine, P.C.  
 Division of Reproductive Endocrinology  
 Department of Obstetrics and Gynecology  
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PRESENT ACADEMIC AND HOSPITAL APPOINTMENTS

1995 Attending Physician, Division of Reproductive Endocrinology  
 Department of Obstetrics and Gynecology, Abington Memorial Hospital,  
 Abington, PA

1995 Attending Physician, Department of Obstetrics and Gynecology,  
 Lower Bucks Hospital, Bristol, PA

1995 Attending Physician, Department of Obstetrics and Gynecology,  
 Doylestown Hospital, Doylestown, PA

1995 Clinical Assistant Professor, Division of Reproductive Endocrinology  
 Department of Obstetrics and Gynecology, Jefferson Medical College,  
 Philadelphia, PA

1995 Visiting Scientist, Department of Molecular Biology, Lehigh University,  
 Bethlehem, PA

1996 Associate Professor, Department of Obstetrics and Gynecology and Reproductive  
 Sciences, Temple University School of Medicine, Philadelphia, PA

1998 Medical Director, In Vitro Fertilization Program, The Toll Center for  
 Reproductive Medicine, Abington Memorial Hospital, Abington, PA

2003 Attending Physician, Division of Reproductive Endocrinology  
 Department of Obstetrics and Gynecology, Albert Einstein Medical Center,  
 Philadelphia, PA

2003 Attending Physician, Division of Reproductive Endocrinology  
 Department of Obstetrics and Gynecology, Holy Redeemer Hospital,  
 Meadowbrook, PA

2007 Attending Physician, Division of Reproductive Endocrinology  
 Department of Obstetrics and Gynecology, Grandview Hospital Sellersville, PA

2009 Clinical Preceptor, Physician Assistant Program, Arcadia University

2014 Professor, Department of Obstetrics and Gynecology and Reproductive Sciences,  
 Temple University School of Medicine

2014 Director, Division of Reproductive Endocrinology

Department of Obstetrics and Gynecology, Abington Memorial Hospital,  
Abington, PA

## EDUCATION

1982 B.A./B.A., (Biology/German) Lehigh University, Bethlehem, PA  
1986 Ph.D., (Reproductive Toxicology and Pharmacology) Duke University, Durham, NC  
1989 M.D., University of North Carolina at Chapel Hill, Chapel Hill, NC  
1993 Residency, Obstetrics and Gynecology, Duke University Medical Center, Durham, NC  
1995 Fellowship, Reproductive Endocrinology and Fertility, Memorial Hospital-University of North Carolina at Chapel Hill, Chapel Hill, NC

## HONORS AND AWARDS

1978 Freshman Lehigh University Honors  
1979 Baylor College of Medicine Summer Student Program in Cell Biology  
1980 Baylor College of Medicine Summer Student Program in Cell Biology  
1981 Omicron Delta Kappa, (ODK) Leadership Honor Society  
1982 National Institutes of Health Predoctoral Traineeship Award  
1985 Sigma Xi, Scientific Honor Society  
1985 National Institutes of Health Pharmacology Research Associate Award (PRAT)  
1986 Society of Toxicology Predoctoral Award  
1986 Duke University Graduate School Honors  
1988 Society of Toxicology Predoctoral Award  
1986 Recipient of Student Foreign Fellowship for Study Abroad, UNC School of Medicine  
1987 First Place Poster Award at Student Research Day, UNC School of Medicine  
1988 UNC School of Medicine Senior Year Honors  
1992 First Pace Award, Resident Research Day Competition, Duke University OB/GYN  
1993 First Pace Award, North Carolina ACOG Annual Meeting Resident's Research Paper Competition  
1994 Second Prize, District IV ACOG Annual Meeting, Poster Presentation  
1999 "Top Doc" for Women's Health in Infertility, Philadelphia Magazine  
2006 Society for Male Reproductive Urology Travel Award (SMRU) to present poster at Annual ASRM meeting  
2009 "Top Doc" for Women's Health in Infertility, Philadelphia Magazine  
2012 "Top Doc" for Women's Health in Infertility, Philadelphia Life Magazine  
2015 "Top Doc" for Women's Health in Infertility, Main Line Today  
2017 "Top Doc" for Women's Health in Infertility, Philadelphia Magazine  
2018 "Top Doc" for Women's Health in Infertility, Philadelphia Magazine  
2019 "Top Doc" for Women's Health in Infertility, Philadelphia Magazine



#### SPECIALTY BOARD CERTIFICATIONS

- 1996 Board Certified, American Board of Obstetrics and Gynecology
- 1998 Board Certified, American Board of Obstetrics and Gynecology, Subspecialty Reproductive Endocrinology and Infertility

#### LICENSURE

- 1990 North Carolina
- 1995 Commonwealth of Pennsylvania Licensed Physician and Surgeon

#### PREVIOUS ACADEMIC AND HOSPITAL APPOINTMENTS

- 1982 Research Associate, Smith Kline and French Laboratories
- 1986 Postdoctoral Associate, Duke University Department of Pharmacology
- 1987 National Institutes of Environmental Health Sciences (NIEHS) Visiting Scientist
- 1989-93 Clinical Instructor, Obstetrics and Gynecology, Duke University
- 1993-95 Clinical Instructor, Reproductive Endocrinology, Obstetrics and Gynecology, University of North at Carolina Chapel Hill

#### EDITORIAL ACTIVITIES

- 1989-94 Abstract Referee, Society for the Study of Reproduction
- 1992- Manuscript Referee, Reproductive Toxicology
- 1993- Manuscript Referee, Obstetrics and Gynecology
- 1995- Editorial Board, Reproductive Toxicology
- 1995- Manuscript Referee, Fertility and Sterility
- 1999- Advisory Panel, Obstetrics and Gynecology Management
- 2004- Conceive Magazine Editorial Board
- 2007- Editor-in-Chief Archives of the Hungarian Medical Society of America

#### PROFESSIONAL ORGANIZATION MEMBERSHIPS AND POSITIONS

- 1982- Society of Toxicology
- 1984- American Society of Andrology
- 1986- North Carolina Medical Society
- 1986-89 American Medical Students Association
- 1987- Hungarian-American Medical Association of America
- 1992- American Society for Reproductive Medicine
- 1995- The Obstetrical Society of Philadelphia

- 1996- The Society for Male Reproduction and Urology
- 1997- Fellow American College of Obstetricians and Gynecologists, (FACOG)
- 1998- The Society for Reproductive Endocrinology and Infertility
- 1998- Board of Directors, Hungarian American Medical Association of America
- 2000- Consultant to the Obstetrics and Gynecology Devices Panel of the Medical Devices Advisory Committee, Center for Devices and Radiological Health, Food and Drug Administration (FDA)
- 2004- Board of Directors, Opera Company of Philadelphia
- 2007- Board member, Philadelphia Area Reproductive Endocrinology Society (P.A.R.E.S.)
- 2008- Board of Directors, Pennsylvania Academy of Fine Arts
- 2009- President-elect, Philadelphia Area Reproductive Endocrinology Society (P.A.R.E.S.)
- 2009- President, Hungarian American Medical Association of America
- 2010- President, Philadelphia Area Reproductive Endocrinology Society (P.A.R.E.S.)

#### TEACHING POSITIONS

- 1989-93 Clinical Instructor, Duke University Medical Center, Medical Students Obstetrics and Gynecology Rotations
- 1987-95 Lecturer, Duke University, Mammalian Toxicology Course, Graduate Students
- 1993-95 Clinical Instructor, University of North Carolina at Chapel Hill, Medical Student Core Lecture in Reproductive Biology
- 1995- Member, Ph.D. Dissertation Committee, Lehigh University
- 1995- Member, Resident Education Committee, Abington Memorial Hospital Residency Program in Obstetrics and Gynecology
- 1995- Clinical Assistant Professor, Division of Reproductive Endocrinology Department of Obstetrics and Gynecology, Jefferson Medical College
- 1996- Associate Professor, Department of Obstetrics and Gynecology and Reproductive Sciences, Temple University School of Medicine
- 2009- Clinical Preceptor, Physician Assistant Program, Arcadia University
- 2014- Professor, Department of Obstetrics and Gynecology and Reproductive Sciences, Temple University School of Medicine

#### RESEARCH GRANTS AND ONGOING STUDIES

- 1995-97 American Society for Reproductive Medicine/TAP Pharmaceuticals Research Grant in Reproductive Endocrinology. Growth Factor Regulation of Human Uterine Receptivity Markers in the Peri-implantation Period, \$20,000. Principal Investigator: Stephen G. Somkuti, M.D., Ph.D.
- 1994-96 American College of Obstetricians and Gynecologists/Ciba Pharmaceutical Company Fellowship for Research in Endocrinology of the Postreproductive Woman. Integrin Expression in Cultured Human Endometrial Epithelium: An in vitro Study Characterizing Markers of Uterine Receptivity, \$25,000. Principal Investigator: Stephen G. Somkuti, M.D., Ph.D.
- 1996 Serono Laboratories: An open label, multicenter, non-comparative phase 3, outpatient study to assess the safety of recombinant LH (r-LH) for compassionate use in patients undergoing ovulation induction for multiple follicular development for assisted reproductive technologies.
- 1999- Participant in multicenter trial, Jefferson Medical College, Division of Reproductive Endocrinology: Multicenter randomized trial of the use of the Insulin sensitizing agent metformin in anovulatory polycystic ovary patients.
- 1999 Ferring Pharmaceuticals, Inc. Randomized open label multicenter study evaluating the efficacy of purified FSH in anovulatory and oligoovulatory female patients for ovulation induction.
- 1999 Jefferson Medical College, Division of Pediatric Endocrinology, Genetics of Ovarian Failure.
- 1999- Lehigh University, Department of Biology. Anti-zonapellucida antibodies in women with premature ovarian failure.
- 2000-1 Ferring Pharmaceuticals, Inc. Randomized open label multicenter study evaluating the efficacy of purified FSH in female patients for in vitro fertilization.
- 2001- Ferring Pharmaceuticals, Inc. Randomized open label, parallel group, multicenter, efficacy study in anovulatory or oligoovulatory infertile female patients comparing purified Repronex sc, purified repronex im, and repronex sc for ovulation induction.
- 2001- A randomized, open label, parallel group, multicenter, efficacy study comparing purified FSH sc and Follistim sc, In female patients undergoing In vitro fertilization (IVF)
- 2002- Femme Pharma, Inc. A multicenter, prospective, open-label evaluation of the use of intravaginally administered Danazol on patients with moderate to severe pain associated with endometriosis
- 2002- Organon Pharmaceuticals, Inc. Oral contraceptive pretreatment for scheduling in Follistim/Antagon vs. Follistim/Lupron cycles in patients undergoing in vitro fertilization and Intracytoplasmic sperm injection (ICSI) treatment.

- 2002- Biosense Corporation, Inc. An intravaginal devise (Biometer) for use in ovulation prediction and natural family planning.
- 2004- Serono Laboratories. A Prospective, randomized, comparative clinical trial with a new formulation of Gonal-f in ovulation induction (OI).
- 2004- Femme Pharma, Inc. A randomized, double-blind, placebo-controlled, multicenter evaluation of the use of intravaginally administered Danazol versus placebo in subjects with moderate to severe pain associated with endometriosis
- 2005- Ferring Pharmaceuticals. Prospective randomized trial comparing autologous endometrial coculture to convential in vitro fertilization.
- 2005- Innovators' Circle AMH Foundation. Cellular markers of differentiation from epithelial to mesenchymal phenotype in endometriosis are reversed by novel inhibitors of inflammatory pathways.
- 2005- Organon Pharmaceuticals Inc. Does 200 IU give as consistent a response as 225IU in normal responding IVF/ICSI patients using the Follistim Pen to deliver Follistim AQ?
- 2006- Organon. "Pilot Study" Development of a long luteal antagonist protocol to increase protocol to increase follicular recruitment.
- 2006- Xanodyne Pharmaceuticals, Inc. A randomized, double-blind, placebo controlled, parallel group, multicenter study to evaluate efficacy and safety of 1.3g oral doses of XP12B-MR tid administered during menstruation for the treatment of menorrhagia.
- 2006- Wyeth Pharmaceuticals, Inc. A double-blind, placebo-controlled study to evaluate the safety and efficacy of 75mg and 150 mg doses of ERB-041 on the reduction of symptoms associated with endometriosis during treatment and after treatment in reproductive aged women.
- 2007- EMD Serono. A phase II, multicenter, randomized, assessor blinded, active comparator, dose finding study to evaluate AS900672-enriched versus follitropin alpha (Gonal-f<sup>®</sup>) in stimulating multiple follicular development in infertile women undergoing assisted reproductive technology (ART).
- 2007- Irvine Scientific. Oocyte cryopreservation by vitrification.
- 2007- Xanodyne Pharmaceuticals, Inc. A multi-center, open label extension study to evaluate the safety of 1.3g oral dose of XP12B-MR tid administered during menstruation for the treatment of menorrhagia
- 2008- Lehigh University Department of Molecular Biology. The effect of serum from ovarian hyperstimulation syndrome (OHSS) patients on expression of Vascular

- endothelial growth factor (VEGF) levels in a porcine in vitro vascular endothelium model.
- 2008- Abington Memorial Hospital Innovators Circle Grant. A randomized trial of vibroacoustic harp therapy in IVF-ET
  - 2008- Schering Plough Corp. Development of a long luteal antagonist protocol to increase follicular recruitment
  - 2009- Biocoat, Inc. Effectiveness of the use of PICS (Hyaluronan Microdot) in the selection of sperm for intracytoplasmic sperm injection (ICSI) for patients having a low versus high proportion of hyaluran binding sperm (HBA)
  - 2009- Humigen, LLC, Genomic Immunoepidemiology Laboratory, Markers for genetic predisposition to infertility and repeated pregnancy loss.
  - 2010- Schering Plough Research Institute, A Phase 3, randomized, double-blind, active-controlled, non-inferiority trial to investigate the efficacy and safety of a single injection of SCH 900962 (corifollitropin alfa) to induce multifollicular development for controlled ovarian stimulation (COS) using daily recombinant FSH (recFSH) as a reference in women aged 35 to 42 years
  - 2011- EMD Serono, Exploratory, non-interventional study to identify and validate biomarkers in follicular fluid, cumulus or granulosa cells or embryo culture media for prediction of implantation and pregnancy outcome of Assisted Reproductive Technology cycle
  - 2013- Abington Memorial Hospital Innovators Circle Grant. Lymphocyte Telomeric Assays as Predictors of Ovarian Reserve & Reproductive Aging
  - 2014- Finox, AG, A Phase III Study to Compare Efficacy and Safety of AFOLIA vs. Gonal-f® in Infertile Women 35 to 42 Years of Age Undergoing in Vitro Fertilization (IVF)
  - 2015- Abington Memorial Hospital Innovators Circle Grant. Tailored amorphous multi-porous bioactive scaffolds (TAMP): a new substrate for the ex-utero development of mouse embryos. Joint Project with Lehigh University Department of Molecular Biology and Material Sciences
  - 2015- Ferring International Pharmascience Center US Inc. MEGASET: A Randomized, Assessor-blind Trial Comparing MENOPUR® (menotropins for injection) and Recombinant FSH (Follicle Stimulation Hormone) in a GnRH Antagonist Cycle with Single-Blastocyst Transfer in a High Responder Subject Population
  - 2018- Ferring International Pharmascience Center US Inc. A Randomized, Double-blind, Placebo-controlled, Parallel Groups, Multicenter Trial Investigating the Efficacy and Safety of FE 999049 in Controlled Ovarian Stimulation in Women Aged 18-34 Years Undergoing Assisted Reproductive Technology

2018- Ferring International Pharmascience Center US Inc. A Randomized, Double-blind, Placebo-controlled, Parallel Groups, Multicenter Trial Investigating the Efficacy and Safety of FE 999049 in Controlled Ovarian Stimulation in Women Aged 35-42 Years Undergoing Assisted Reproductive Technology

#### BIOTECHNOLOGY AND PHARMACEUTICAL INDUSTRY CONSULTANCIES

AbbVie  
Adeza Biomedical  
Biosense Corporation  
Cytec Corporation  
EMD Serono  
Femme Pharma  
Ferring Pharmaceuticals  
Irvine Scientific  
Merck  
Pamlab  
pH Diagnostics  
Schering Plough  
Sage  
Wyeth  
Xanodyne Pharmaceuticals

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German

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Moore, M.R. and Somkuti S.G. Pediatric and Adolescent Gynecology in Pearls of Obstetrics and Gynecology (2014) McGraw Hill

Somkuti, S.G. editor Pearls of Obstetrics and Gynecology (2013) Fourth Edition McGraw Hill

Acs, G., and Somkuti, S.G. editors 50 years: History of the Hungarian Medical Association of America (2018), Debrecen Press

## MEDIA

1998: Wyeth Ayerst Laboratories Promotional video on Crinone 8% Progesterone Vaginal Gel use in Assisted Reproductive Technologies

1998: "Medical Answers: Infertility" WNVT-TV Public Broadcasting System 10-11PM  
November 25th, 1998



1999: “Let’s Talk Health: Infertility” WPHT 1210AM Radio Talk show March 7, 1999

1999: Channel 3 KYW TV interview on IVF March 30, 1999

1999: KYW 1210 AM Talk Radio interview on IVF April 2, 1999

2003: Philadelphia Inquirer Article “The Bad Gene Stops Here” February 3 issue

2003: Channel 17 WB “The Bad Gene Stops Here” news segment on Preimplantation Genetic Diagnosis

2004: Channel 6 WPVI “Ovulation Predictor Devices” interview May 13, 2004

2006: Voice America Internet Radio; Conceive on Air “The Next steps” in infertility evaluation radio Talk Show May 31, 2006

2006: Voice America Internet Radio; Conceive on Air “Preimplantation Genetic Diagnosis” radio Talk Show December, 2006

#### INVITED LECTURES

American Hungarian Medical Society Annual Meeting; The Male Reproductive System as a Target of Various Toxicants, Sarasota, October 1987.

American Hungarian Medical Society Annual Meeting; Recent Progress in Infertility Evaluation, Sarasota, October 1990.

American Hungarian Medical Society Annual Meeting; Treatment Approaches to the Patient With Chronic Pelvic Pain, Sarasota, October 1991.

F. Bayard Carter Society of Obstetricians and Gynecologists, 41st Annual Meeting; Between in vivo and in vitro: stage-specific seminiferous tubule cultures as a tool in mechanistic reproductive toxicology, Charleston, October 1992.

Medical Endocrinology/Pediatric Endocrinology Conference at the University of North Carolina Memorial Hospital; Panhypopituitarism, Chapel Hill, April, 1994.

Nash General Medical Center Department of Obstetrics and Gynecology Grand Rounds; Androgen Insensitivity Syndrome, Rocky Mount, April 1994.

Memorial Mission Hospital Grand Rounds; Androgen Secreting Tumors of the Ovary, Asheville, June 1994.



New Hanover Memorial Hospital, Department of Obstetrics and Gynecology Grand Rounds; Alternatives to Hysterectomy: Update of the recent NIH conference, Wilmington, August 1994.

F. Bayard Carter Society of Obstetricians and Gynecologists, 44th Annual Meeting; Transvaginal Ultrasound Assessment of Uterine Receptivity, Durham, September 1994.

National Institutes of Environmental Health Sciences Reproductive Biology Seminar Series; Characterization of Integrin Expression in Human Endometrium, Research Triangle Park, January 1995.

Maria Parham Hospital Grand Rounds; Endocrine Etiologies of Amenorrhea, Henderson, February 1995

New Hanover Memorial Hospital, Department of Obstetrics and Gynecology Grand Rounds; Hyperprolactinemia, Wilmington, March 1995.

Lehigh University, Department of Molecular Biology Seminar, Integrins as Markers of Uterine Receptivity, March, 1995.

New Hanover Memorial Hospital, Department of Pediatrics Grand Rounds; Precocious Puberty, Wilmington, April 1995.

Jefferson Medical College, Serono Symposia USA, Insights into Infertility: Challenges and Choices, Advanced Reproductive Technologies, March 1996.

Jefferson Medical College, Serono Symposia USA, Insights into Infertility: Challenges and Choices, Ovulation Induction Strategies, March 1997.

Abington Memorial Hospital Grand Rounds, Abington, PA, Assisted Reproductive Technologies, September 1998

Abington Memorial Hospital School of Nursing, Abington, PA, Update in In vitro Fertilization, January 2000

Abington Memorial Hospital Grand Rounds, Abington, PA, Fertility Preservation Options after Cancer, October 2003

Greater Baltimore Medical Center, Baltimore, MD, Patient Preference for Gonadotropin Products in the Context of Patient-Centered Care May, 2005

Huntingdon's Society Annual Meeting Philadelphia, PA, Preimplantation Genetic Diagnosis Options for Huntingdon's Disease, April 2006

Northshore Medical Center, Manhasset, NY, Reducing Infertility Patient Dropout, October 2008

Fox Chase Cancer Center, Fox Chase, PA, Cancer and Fertility Preservation Options

September, 2009

Lehigh University, Department of Molecular Biology Seminar, The Diagnostic Dilemma of Identical (monozygotic) Male/Female Twin Siblings, October, 1997.

Jefferson Medical College, Serono Symposia USA, Insights into Infertility: Challenges and Choices, Advances in In Vitro Fertilization, November 1998.

Pennsylvania Hospital, Greater Philadelphia Comprehensive OB/GYN Review Course, Spontaneous Abortion, Recurrent Abortion, and Ectopic Pregnancy, April 10, 1999.

Research Triangle Area Reproductive Endocrinologists, Towards optimizing Blastocyst Development, Chapel Hill, October 1999

University of Florida, Division of Reproductive Endocrinology, Towards optimizing Blastocyst Development, Gainesville, October, 1999

Jefferson Medical College, Assisted Reproductive Technologies Symposium, November 1999.

Pennsylvania Hospital, Greater Philadelphia Comprehensive OB/GYN Review Course, Spontaneous Abortion, Recurrent Abortion, and Ectopic Pregnancy, April 8, 2000.

Chestnut Hill Hospital, Department of Obstetrics and Gynecology Grand Rounds, Advances in ART, Chestnut Hill, May 2001

Pennsylvania Pharmacists Association, The Newest Gonadotropin Therapies, Philadelphia, July, 2002

American Hungarian Medical Society Annual Meeting; Autologous endometrial coculture, Sarasota, October 2003.

American Hungarian Medical Society Annual Meeting; Ovulation Prediction, Sarasota, October 2004.

American Hungarian Medical Society Annual Meeting; Cellular markers of differentiation from epithelial to mesenchymal phenotype in endometriosis are reversed by novel inhibitors of inflammatory pathways, Sarasota, October 2006.

Monthly Medical Student and OB/GYN resident reproductive endocrinology and infertility lecture series

Huntingdon's Society Annual Meeting; Preimplantation Genetic Diagnosis for Huntingdon's Disease, Philadelphia, October 2009

Abington Memorial Hospital: Primary Care Update: 2010 Women's Health Focus: Infertility, Abington, June 2010

Abington Memorial Hospital Grand Rounds, Abington, PA, Oocyte Cryopreservation, February 2010

Huntingdon's Society Annual Meeting Philadelphia, PA, Preimplantation Genetic Diagnosis Options for Huntingdon's Disease April 2010

University of Alabama Birmingham, Birmingham, AL, The Present and Future Embryo Quality Assessment, November 2010

Lower Bucks Hospital Grand Rounds, Bristol, PA, Preimplantation Genomic Screening, January 2011

Albert Einstein Medical Center, Philadelphia, PA. Division of Oncology Grand Rounds, Cancer and Fertility, July, 2011

American Hungarian Medical Society Annual Meeting; Autologous endometrial coculture, Sarasota, October 2012

American Hungarian Medical Society Annual Meeting; Towards Single embryo transfer, Avoidance of Multiple Pregnancy", Sarasota, October 2014

American Hungarian Medical Society Annual Meeting; Reproductive Outcomes Robotic versus Open Myomectomy, Sarasota, October 2016

American Hungarian Medical Society Annual Meeting; The Transgender Man: fertility Preservation options and Pregnancy outcomes, Sarasota, October 2017

American Hungarian Medical Society Annual Meeting; 50 Years of Advances in Reproductive Medicine, Sarasota, October 2018

AMERICAN HUNGARIAN MEDICAL SOCIETY ANNUAL MEETING; SIBLING GAMETE DONATION TO MONOZYGOTIC TWIN RECIPIENTS WITH PREMATURE OVARIAN FAILURE, SARASOTA, OCTOBER 2019

#### DEPOSITIONS PAST 4 YEARS

##### **September, 2019 Boyle v. El-Roeiy, et al**

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**May, 2015 Kelsey Violanti v. Young B. Kim, M.D.**

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**May, 2014 Jamyra Vadis v. Jan Anthony Oleginski, D.O.,  
Milind Vaze, M.D., Aria Health Frankford campus and Aria Health System  
File No. 185-631**

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